Commonwealth of Kentucky
Division for Air Quality

PERMIT STATEMENT OF BASIS

(FINAL)
Conditional Major / Synthetic Minor, Operating
Permit: F-05-041 R1
Catalent Pharma Solutions, LLC
Winchester, KY 40391
March 10, 2008
Julian D. Breckenridge, Reviewer

SOURCE ID:	21-049-00040
AGENCY INTEREST:	813
ACTIVITY:	APE20060001 & APE20070001

MINOR REVISION FOR F-05-041 R1

On November 7, 2006, the source submitted an application to the Division for Air Quality for a request to modify the language in the compliance demonstration section for catalytic oxidizers covered under Section 17 of 401 KAR 52:030, Off-Permit and Section 502(b)(10) Changes. A letter dated for February 21, 2007 was sent out to the source, granting the request at the next significant revision for the Compliance Demonstration Method under Section B on page 14 of the permit in paragraph c) to replace the current statement with the following:

> c) *The above emission units shall be operated only when the average catalyst bed inlet temperature for the controlling catalytic oxidizer is maintained from 450℉ to 650℉.*

The Division incorporated this change into permit # F-05-041 R1. Moreover, on August 21, 2007 another application was received for the addition of a New Pan Coater as an insignificant activity along with a name/ownership change. The source formerly known as Cardinal Health PTS, LLC is now called Catalent Pharma Solutions, LLC. Due to a Notice of Deficiency (NOD) response received on January 31, 2008, the source has made updates to its plant-wide facility of the removal of certain emission points and the changes to the maximum operating rates and emission factors of various emission points (See the following table in the Comments Section). The application was deemed complete on March 4, 2008.

SOURCE DESCRIPTION:

Catalent Pharma Solutions, LLC (formerly Cardinal Health Inc.) produces food, pharmaceutical and chemical products by using various solvents in granulation, coating and drying operations. Primary emission units include pharmaceutical processing units, as well as boilers and storage tanks. The processing units utilize aqueous or solvent solutions to produce the pharmaceuticals. Solvents used in the production of solvent-based pharmaceutical products include Ethanol, Isopropanol, Acetone, Methanol, and Methyl Ethyl Ketone, with a small amount of Acetonitrile used in the QC lab. The volatile organic compounds emitted through solvent processing are controlled by catalytic oxidizers. The Standard Industrial Classification (SIC) Code for this source is 2834, *Pharmaceutical Preparations*.

The potential to emit (as defined in 401 KAR 52:001, Section 1 (56)) of volatile organic compounds (VOC), any single hazardous air pollutant (HAP), and the combination of HAPs are greater than major source thresholds. The uncontrolled potential to emit of particulate matter less than 10 microns (PM_{10}) is greater than one hundred (100) tons per year and is allowed by limitations of 401 KAR 59:010. To preclude the applicability of 401 KAR 52:020, *Title V Permits*, and 401 KAR 51:017, *Prevention of Significant Deterioration of Air Quality (PSD)*, the source has requested voluntary federally enforceable permit limits below major source thresholds. Therefore, the source is subject to the provisions of 401 KAR 52:030, *Federally-enforceable permits for non-major sources*.

COMMENTS:

(1) Emission Units:

The following table provides a concise summary of the emission units at this source by emission point number and any changes or updates at the source since the issuance of permit F-05-041, as requested by the permittee.

Emission Points - Current Status		Explanation of Change
EP #	**Emission Point Description**	
09	Room 114, Boiler #1 and #2 4.0 mmBtu/hr each	No change
26	Room 141, Boiler #3 4.0 mmBtu/hr	No change
50	Room 5, Boiler #4 14.65 mmBtu/hr	No change
10	Catalytic Oxidizer #1 Backup Oxidizer	Correction to the control efficiency: 95%
22	Catalytic Oxidizer #2 Primary Oxidizer	No change
36	Catalytic Oxidizer #3	No change
01	Room 105, CPCG-60 Maximum rating: 38.5 lb/hr Solvent Control: Ox #3	Change in maximum operation rate (APE20070001)
03	Room 111, CPCG-300 Maximum rating: 179 lb/hr Solvent Control: Ox #2	Change in maximum operation rate (APE20070001)
04	Rooms 109, 110 and 111, Fugitive Dust Collector Maximum Rating: 5 lb/hr	No change
05	Room 109, 110 and 111 Vac-U-Max Powder Conveyor Maximum rating: 1000 lb/hr	No change
06	Four (4) Portable Solvent Charging Kettles; Between 15-300 gallons each (average 115 gallons), Insignificant activity	No change
07	Room 109, CPCG-300 Maximum rating: 132 lb/hr Solvent Control: Ox #2	Change in maximum operation rate (APE20070001)
08	Room 206, Two (2) PanCoaters 48", PC-1500 Maximum rating: 151 lb/hr total	Change in maximum operation rate (APE20070001)
11	Room 108, CPCG-300 Maximum rating: 355 lb/hr Solvent Control: Ox #2	Change in maximum operation rate (APE20070001)

Emission Points - Current Status		Explanation of Change
EP #	Emission Point Description	
13	Room 108, Powder Conveyor Maximum rating: 1000 lb/hr	No change
14	Area 1 Central Vacuum System	No change
15a	Room 103, CPCG-15 Maximum rating: 30 lb/hr Solvent Control: Ox #3	Change in maximum operation rate (APE20070001)
15b	Room 103, Pilot PC-1500 Maximum rating: 27 lb/hr Solvent Control: Ox #3	Change in maximum operation rate (APE20070001)
16	Rooms 103 and 105, Fugitive Dust Collector	No change
17	Room 132, PC-1500 Maximum rating: 45 lb/hr Solvent Control: Ox #3	Change in maximum operation rate (APE20070001)
18	Room 136, CPCG-300 Maximum rating: 16 lb/hr Solvent Control: Ox #2	Change in maximum operation rate (APE20070001)
19	Area 2 Northside Central Vacuum System Maximum rating: 2400 lb/hr	Change in maximum operation rate (APE20070001)
20	Rooms 133 and 135, Powder Conveyor Maximum rating: 1000 lb/hr	No change
21	Room 218 CPCG-120 Maximum rating: 43 lb/hr Solvent Control: Ox #2	Change in maximum operation rate (APE20070001)
23	Room 219 Tray Dryer Maximum rating: 100 lb/hr	No change
24	Northside Process Rooms Fugitive Dust Collector	No change
25	Southside Process Rooms Fugitive Dust Collector	No change
27	Four (4) Portable Solvent Charging Kettles; Between 15-300 gallons each (average 115 gallons), Insignificant activity	No change
28	Bulk Tank 1, 3,500 gallons	No change
29	Bulk Tank 2, 4,000 gallons	No change
30	Bulk Tank 3, 3,500 gallons	No change
31	Bulk Tank 4, 4,000 gallons	No change
32	Area 2 Southside Central Vacuum System Maximum rating: 2400 lb/hr	No change
33	Room 35 CPCG-3 Maximum rating: 5 lb/hr	Removed from the plant
34	Room 121 Solution Preparation Tank #1 Maximum rating: 600 gallons	Insignificant Activity No change
35	Room 121 Solution Preparation Tank #2 Maximum rating: 600 gallons	Insignificant activity
46	Room 108A CF Granulator Maximum rating: 352 lb/hr	Removed from the plant
47	Room 108A Fugitives	Insignificant activity
49	Warehouse #2 PC-1500 Maximum rating: 131 lb/hr	Change in maximum operation rate (APE20070001)
76	New Pan Coater PC-3000	Insignificant activity

(2) All of the insignificant activities are included in Section C of permit F-05-041 R1.

(3) Emission Factors: AP-42, Chapter 1.4, Tables 1.4-1 and 1.4-2 were used to determine the natural gas combustion emissions from Boilers No. 1, 2, 3 and 4. Emissions from the Coating/Granulation Units, Conveyor Systems and Supporting Equipment were calculated based on raw material usage rates and material balance, as provided by the permittee. Potential VOC and HAPs emissions from the storage tanks were calculated using U.S. EPA TANKS program, with results provided by the permittee.

(4) Applicable Regulations:

(a) 401 KAR 59:010, *New process operations*

Pursuant to 401 KAR 59:010, Section 1, the requirements of this rule apply to each affected facility, associated with a process operation, which is not subject to another emission standard with respect to particulates in 401 KAR Chapter 59, commenced on or after July 2, 1975. For processing rates of 1000 lb/hr or less, the emissions of particulate matter shall not exceed 2.34 lb/hr. For processing rates greater than or equal to 1000 lb/hr but less than 60,000 lb/hr, the emissions shall not exceed 3.59 x (Tons processed per hour)$^{0.62}$ lb/hr. Visible emissions shall not be equal to or exceed 20% opacity. These requirements apply to the following emission units:

EP#	DESCRIPTION	ALLOWABLE PM (lb/hr)
01	Room 105, Glatt CPCG-60	2.34
03	Room 111, Glatt CPCG-300	2.34
04	Rooms 109, 110 and 111, Fugitive Dust Collector	2.34
05	Rooms 109, 110 and 111, Pneumatic Powder Conveyor	2.34
07	Room 109, Glatt CPCG-300	2.34
08	Room 206, Two (2) PanCoater 48” PC-1500	2.34
11	Room 108, Glatt CPCG-300	2.34
13	Room 108, Pneumatic Powder Conveyor	2.34
14	Area 1 Central Vacuum System	4.95
15a	Room 103, Glatt CPCG-15	2.34
15b	Room 103, Pilot PanCoater 24” PC-1500	2.34
16	Rooms 103 and 105, Fugitive Dust Collector	2.34
17	Room 132, PanCoater 48” PC-1500	2.34
18	Room 136, Glatt CPCG-300	2.34
19	Area 2 Northside Central Vacuum System	4.02
20	Rooms 133 and 135, Pneumatic Powder Conveyor	2.34
21	Room 218, Glatt CPCG-120	2.34
24	Northside Process Rooms Fugitive Dust Collector	3.00
25	Southside Process Rooms Fugitive Dust Collector	3.00
32	Area 2 Southside Central Vacuum System	4.02

EP#	DESCRIPTION	ALLOWABLE PM (lb/hr)
49	Warehouse 2, PanCoater 60" ACPC-3000	2.34

(b) 401 KAR 59:015, *New indirect heat exchangers*, applies to Boilers no. 1, 2, 3, and 4 because each of these indirect heat exchangers commenced after April 9, 1972 and has a heat input capacity of more than one (1) million British thermal units per hour (mmBtu/hr). Pursuant to 401 KAR 59:015, Sections 4(1) and 5(1) respectively, the allowable particulate matter (PM) and sulfur dioxide (SO_2) emission limits are calculated as follows:

(i) For boilers no. 1 and 2 (rated at 4.0 mmBtu/hr each and constructed in 1992, for a total rated heat input rating of the source of 8.0 mmBtu/hr):

PM emission limit = 0.56 lb/mmBtu
SO_2 emission limit = 3.0 lb/mmBtu

(ii) For boiler no. 3 (rated at 4.0 mmBtu/hr and constructed in 1997):

PM emission limit = 0.56 lb/mmBtu
SO_2 emission limit = 3.0 lb/mmBtu

(iii) For boiler no. 4 (rated at 14.65 mmBtu/hr and constructed in 2004):

PM emission limit = 0.9634 x (total heat input rating for the source)$^{-0.2356}$
PM emission limit = 0.9634 x $(14.65)^{-0.2356}$ = 0.51 lb/mmBtu

SO_2 emission limit = 7.7223 x (total heat input rating for the source)$^{-0.4106}$
SO_2 emission limit = 7.7223 x $(14.65)^{-0.4106}$ = 2.56 lb/mmBtu

Also, pursuant to 401 KAR 59:015, Section 4(2), the opacity of visible emissions from Boilers no. 1, 2, 3 and 4 each shall not exceed 20%.

(c) 401 KAR 60:005, which incorporates by reference 40 CFR 60, Subpart Dc, *Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units* applies to Boiler No. 4 rated at 14.65 mmBtu per hour because the boiler was constructed after the rule applicability date of June 9, 1989 and the boiler is rated at less than one hundred (100) mmBtu, but greater than ten (10) mmBtu per hour. Pursuant to 40 CFR 60.48c(g)(2), the permittee shall monitor and record the amount of natural gas combusted during each calendar month.

Boilers no. 1, 2 and 3 are not subject to the requirements of Subpart Dc because operation commenced before the rule applicability date of June 9, 1989 and the maximum heat input ratings are less than the rule applicability threshold of 10 mmBtu/hr.

(d) 401 KAR 63:020, *Potentially hazardous matter or toxic substances*
This rule requires that persons responsible for a source from which hazardous matter or toxic substances may be emitted shall provide the utmost care and consideration, in the handling of these materials, to the potentially harmful effects of the emissions resulting from such activities. No owner or operator shall allow any affected facility to emit potentially hazardous matter or toxic substances in such quantities or duration as to be harmful to the health and welfare of humans, animals and plants.

The source is subject to 401 KAR 63:020. To show compliance with this rule and ambient air quality standards in 401 KAR 53:010, in permit F-05-041 the permittee had conducted an air dispersion modeling analysis of source emissions of ethanol, isopropyl alcohol (IPA), acetone, methanol, methyl ethyl ketone (MEK), acetonitrile, particulate matter and nitrogen oxides (NO_x). The analysis utilized the U.S. EPA's SCREEN3 air dispersion model. Based on the results of the modeling impact evaluation, the permittee has demonstrated compliance with the requirements of 401 KAR 63:020. If the permittee alters process rates, material formulations, or any other factor that would result in an increase of toxic emissions or the addition of toxic emissions not previously evaluated by the Division, the source shall submit the appropriate application forms pursuant to 401 KAR 52:030, Section 3(1)(a), and modeling may be required to show that the facility will remain in compliance with 401 KAR 63:020.

(5) Non-Applicable Regulations:

(a) The permittee has requested voluntary permit emission limits of 90 tons per year (tpy) or less of VOC, 90 tpy or less of PM/PM_{10}, 9 tpy or less of a single (HAP), and 22.5 tpy or less of combined HAPs. As such, this source will not be a major source of HAP emissions, and there are no *NESHAPs* (40 CFR 63 and 401 KAR 63) applicable to this area source for HAP emissions, as such is defined at 40 CFR 63.2. Compliance with above emission limits shall also make the requirements of 401 KAR 52:020, *Title V Permits*, and 401 KAR 51:017, *Prevention of significant deterioration of air quality* (PSD), not applicable to the source.

(b) 401 KAR 60:005, which incorporates by reference 40 CFR 60, Subpart Kb (40 CFR 60.112b), *Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced after July 23, 1984* does not apply to any of the storage tanks (Emission Points 28, 29, 30 or 31 and Emission Points 06, 27, 34 and 35 listed as insignificant activities) since the storage rating of each tank is less than 75 m^3 (19,812 gallons).

(c) 401 KAR 59:050, *New storage vessels for petroleum liquids*, does not apply to the four (4) bulk storage tanks #1 - #4 (EP 28 - EP 32) because these tanks do not store petroleum liquids as defined in the rule.

EMISSION AND OPERATING CAPS DESCRIPTION:

Clark County is designated as attainment for all criteria pollutants. To preclude the applicability of 401 KAR 52:020, *Title V permits*, total annual source-wide emissions shall not exceed the following specific limitations on a twelve (12) consecutive month basis:

(a) Volatile organic compound (VOC) emissions: 90 tons per year;
(b) Particulate matter (PM/PM_{10}) emissions: 90 tons per year;
(c) Combined hazardous air pollutant (HAP) emissions: 22.5 tons per year; and
(d) Single hazardous air pollutant (HAP) emissions: 9 tons per year.

Compliance with these limits shall also make the requirements of 40 CFR Part 63 for major sources of HAP emissions, as incorporated by reference at 401 KAR 63:002, not applicable to this source. Compliance with these limits shall also make the requirements of 401 KAR 51:017, PSD, not applicable to this source.

PERIODIC MONITORING:

To preclude the applicability of 401 KAR 52:020, *Title V Permits*, and 401 KAR 51:017, PSD, the source-wide emissions are limited to 90 tons per year for VOC, 90 tons per year for PM/PM_{10}, 9 tons per year for any single HAP, and 22.5 tons per year for combined HAPs. The permit requires the source to monitor and keep monthly records of raw material input usage rates and emission rates of VOC, individual HAP, and combined HAP from the Coating/Granulation Units and the storage tanks. The permit also requires the source to monitor and keep monthly records of the dry pharmaceutical material processing rates and emission rates of particulate matter from the Coating/Granulation Units, Conveyor Systems and Supporting Equipment. The permit requires these records to be reported semiannually.

For the Coating/Granulation Units, Catalytic Oxidizers, Conveyor Systems and Supporting Equipment, the pressure drop across each particulate control device shall be monitored and recorded on a weekly basis. For the Catalytic Oxidizers, the permittee shall monitor and record the catalyst bed inlet and outlet temperatures continuously. Three-hour averages shall be recorded every 15 minutes. For the Coating/Granulation Units, Catalytic Oxidizers, Conveyor Systems and Supporting Equipment, the permittee shall operate a broken bag detector on each particulate control device or perform visual observations of the opacity of emissions on a weekly basis from each emission unit while in operation. These records shall be maintained. All records shall be reported semiannually.

OPERATIONAL FLEXIBILITY:

There were no alternative operating scenarios proposed by the permittee.

CREDIBLE EVIDENCE:

This permit contains provisions which require that specific test methods, monitoring or recordkeeping be used as a demonstration of compliance with permit limits. On February 24, 1997, the U.S. EPA promulgated revisions to the following federal regulations: 40 CFR Part 51, Sec. 51.212; 40 CFR Part 52, Sec. 52.12; 40 CFR Part 52, Sec. 52.30; 40 CFR Part 60, Sec. 60.11 and 40 CFR Part 61, Sec. 61.12, that allow the use of credible evidence to establish compliance with applicable requirements. At the issuance of this permit, Kentucky has only adopted the provisions of 40 CFR Part 60, Sec. 60.11 and 40 CFR Part 61, Sec. 61.12 into its air quality regulations.